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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group:	1617
Confirmation No.:	5772
Application No.:	10/031,827
Invention:	ANTIVIRAL THERAPY USE OF P-GLYCOPROTEIN MODULATORS
Applicant:	Alastair J. Wood, et al.
Filed:	January 22, 2002
Attorney Docket:	32808-69752
Examiner:	Travers

Certificate Under 37 CFR 1.8(a)

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office, central fax number 703-872-9306

on December 29, 2003

(Signature)

Joyce Hamilton
(Printed Name)

AMENDMENT AND RESPONSE UNDER 37 U.S.C. § 1.111

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed June 30, 2003, Applicant requests consideration of the accompanying remarks. Applicant requests a three-month extension of time for a response. Please charge $475 for payment of extension of time as well as any additional fees that may be required to the account of Barnes & Thornburg, Deposit Account No. 10-0435, with reference to our matter 32808-69752.

Large entity status was originally claimed and established for the captioned application. Applicants hereby give notice that large entity status is no longer appropriate for the captioned application due to the termination of a license to Eli Lilly and Company. Vanderbilt University, the assignee of the above-captioned application, is a small entity. The undersigned respectfully request that the Patent Office change its records accordingly to reflect proper small entity status.

CYP3A is not suggested or taught by either Kim et al. or Pfister et al. Furthermore, as shown in Fig. 3, the compound of Formula II is actually more effective than various other known P-glycoprotein inhibitors in increasing the concentration of an HIV protease inhibitor, nelfinavir, in both the testes and brain. Similar results were achieved with saquinavir and indinavir. Thus, the co-administration of the compound of Formula II and an HIV protease inhibitor show synergistic effects that were not obvious from the prior art. Accordingly, applicants respectfully submit that at the time the invention was made, the claimed combination was not obvious over Kim in view of Pfister. Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a).

CONCLUSION

The application is believed to be in condition for allowance. Withdrawal of the rejection and passage of the application to issuance is respectfully requested.

Respectfully submitted,
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